

Pregnancy Rapid Test Strip

INSTRUCTIONS FOR USE

PLEASE READ ALL INFORMATION IN THE INSTRUCTIONS FOR USE BEFORE USING THE TEST!

REF See Box label

INTENDED USE

Amazewell™ Pregnancy Rapid Test Strip is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine, as an aid in early detection of pregnancy. It is intended for use by people who would like to find out whether they are pregnant in a home environment.

Only for use outside the body. For over-the-counter (OTC) use.

KIT CONTENT

Material provided

1. One pouch containing a test and a bag of desiccant.
2. Leaflet with instructions for use.

Materials needed but not provided

1. A urine collection cup to collect the urine.
2. Timer or clock.

STORAGE CONDITIONS AND SHELF LIFE

1. Store in dry places at 35 - 86°F (2 - 30°C), **DO NOT freeze.**
2. The product is stable until the expiration date printed on the outer packaging.
3. Use the test strip within 1 hour after removing from the foil.

WARNING AND PRECAUTIONS

1. This product is only for in vitro testing of human urine. **NOT** for internal use.
2. **DO NOT** make any decision of medical relevance without first consulting your doctor.
3. This product is for single-use. **DO NOT reuse.**
4. Keep out of the reach of children.
5. The desiccant in the foil pouch is for storage purposes only. **DO NOT swallow.**
6. **DO NOT** use the test device if damaged or not well sealed.
7. **DO NOT** use the product after the expiration date.
8. Please follow local regulations to discard used product.

SAMPLE REQUIREMENTS

Use the urine collection cup to collect the sample. It is preferable to collect the urine sample first thing in the morning, however, urine samples collected at any time of the day can be used for the test.

Please perform the test immediately after urine collection.

TAKE THE TEST

1. Remove the test strip from foil pouch and use immediately. **Caution: DO NOT touch the sample pad and the result window.**
2. Collect your urine in a urine collection cup. Immediately after collection, holding the test strip vertically, immerse the sample pad into the urine with the arrow pointing towards the urine (Fig.2). **Caution: DO NOT immerse past the MAX line. Make sure that only the sample pad is wet during sampling and that other parts of the test remain dry.**
3. Take the test strip out after 5 seconds. Lay the test strip flat on a clean, dry, non-absorbent surface with the MAX line side facing upwards, and then begin timing. **Caution: Never hold the test strip with the sample pad pointing upwards during testing (Fig.3).**
4. Positive results may sometimes appear as early as 3 minutes, but you should wait the full 5 minutes to confirm a result.
5. **DO NOT** read the result after 10 minutes.

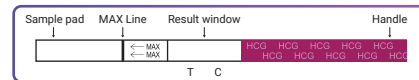


Fig.1 Test Strip

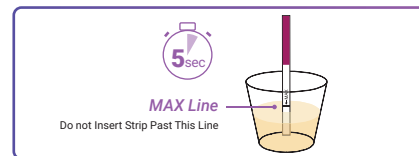


Fig.2 Test in a Container

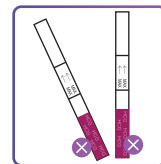
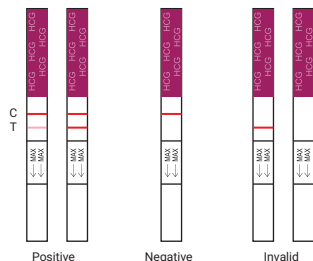


Fig.3 Never hold the test strip with the sample pad pointing upwards during testing



Fig.4 WAIT 5 mins before checking results. NOT after 10 mins.

READ YOUR RESULT



Positive (pregnant): TWO distinct colored lines appear. A colored line is visible in both the Control Zone (C) and the Test Zone (T), the test result is positive and valid. It indicates you are pregnant (See Q1).

Negative (not pregnant): Only ONE colored line appears in the Control Zone (C), and no apparent line in the Test Zone (T), the result is negative and valid. It indicates you are not pregnant (See Q2).

Invalid: No colored line appears in the Control Zone (C), even if a colored line appears in the Test Zone (T), it indicates that the test is invalid (See Q5).

NOTE: If the color in the Test Zone is very faint, it is recommended to repeat the test in 48 hours or if the test shows a negative result, but you suspect that you may be pregnant, repeat the test after a few days.

QUESTIONS & ANSWERS

1. My result is Pregnant. What should I do?

The positive test result may indicate pregnancy. See your doctor to confirm, who can advise you on your next steps.

2. My result is Not Pregnant. What does this mean?

When the test result is negative, it indicates that you may not be pregnant. If pregnancy is still suspected, test again using a new device with morning urine 48-72 hours later. If you still get a negative result and your period is late, you should see your doctor.

3. How does Amazewell™ Pregnancy Rapid Test Strip work?

It uses a sandwich immunoassay to detect the hCG (human Chorionic Gonadotropin) in urine.

4. Can any medication or conditions affect the results?

Medications containing hCG can affect the result. A number of conditions other than pregnancy cause elevated levels of hCG and could cause misleading results. Unclean urine collection containers or improper operation will also produce incorrect results.

5. How do I know that the test was run properly?

The appearance of a colored line in the Control Zone (C) indicates that the test was performed properly. If no colored line appears in the Control Zone (C), even if a colored line appears in the Test Zone (T), it indicates that the test is wrong or invalid. Please make sure that the operation is correct, and retest with a new test strip.

6. What if the colored lines in the Test Zone (T) is very light, am I pregnant?

The test has worked if a colored line appears in the Control Zone (C), and even if the colored line in the Test Zone (T) is very light, you should assume that you are pregnant. Please see your doctor to confirm.

7. The colored lines in the Control Zone (C) differs between the two tests. Is this a concern?

No. Differences in the color of the colored lines in the Control Zone (C) do not affect the test result.

8. Can test results be interpreted after more than 10 minutes?

Test results must be read in 10 minutes. A negative result may change to a false positive within minutes after the end of the 10-minute testing period, which would not be an accurate reading. It is always best to read the result at the 5 minutes and then discard the test to avoid confusion.

ASSISTANCE

Call toll-free **(888) 695-5248** (Monday – Friday 9:00 am – 5:00 pm, EST) or email to **support@dochekusa.com**.

Any serious incident related to the device shall be reported to the manufacturer and the competent authority in your country.

MEANING OF SYMBOLS ON PACKAGE

	Consult instructions for use		Keep dry
	Store at 35°F - 86°F (2°C - 30°C)		Keep away from sunlight
	Use-by date		Catalogue number
	Batch code		Do not reuse
	In vitro diagnostic medical device		Do not use if package is damaged

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